

EXHIBIT 1

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Case No. 2:21-cv-10312

Plaintiff,

Hon. Stephen J. Murphy, III

v.

BLUEWILLOW BIOLOGICS, INC.,

Defendants.

**PLAINTIFF'S ANSWERS TO DEFENDANT'S
FIRST SET OF INTERROGATORIES**

Plaintiff, Trutek Corp. ("Trutek") hereby provides the following answers to Defendants' First Set of Interrogatories.

DEFINITIONS

- The term "Plaintiff" shall mean Trutek.
- The term "Defendant" shall mean BlueWillow Biologics, Inc. ("BlueWillow").
- The term "Asserted Patent" or "Patent-in-Suit" shall mean U.S. Patent No. 8,163,802 ("the '802 Patent") issued to Ashok Wahi on April 24, 2012.

ANSWERS TO INTERROGATORIES

INTERROGATORY No. 1

Identify and describe in detail every product owned, sold, manufactured, designed, created, or licensed by You that you claim practices one or more inventions disclosed or claimed in the asserted patent, including by identifying which claim is practiced by each product and how it is practiced and by identifying the persons most knowledgeable about the information requested in this interrogatory and all documents related thereto.

ANSWER:

1. NasalGuard® Airborne Particle Blocker - Unscented
2. NasalGuard® Airborne Particle Blocker - Cool Menthol
3. NasalGuard® Airborne Particle Blocker - Fine Mist Nasal Spray
4. NasalGuard® Contaminant Blocking Gel - Unscented
5. NasalGuard® Contaminant Blocking Gel - Cool Menthol
6. NasalGuard® Antiseptic Topical Gel - Unscented
7. NasalGuard® Antiseptic Topical Gel - Cool Menthol
8. NasalGuard® Allergie BLOCK
9. NasalGuard® Allergie BLOCK - Cool Sensations
10. NasalGuard® Mask Spray

INTERROGATORY No. 2

Describe in detail the bases for Your infringement assertions, including by:

- (1) identifying each patent claim that You contend has been infringed by the asserted patent or will be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of any accused product (“asserted claims”),
- (2) identifying each product of BlueWillow that you accuse of infringing each such claim (“accused product(s)”),
- (3) providing a claim chart that identifies and explains with specificity how each element of the accused product(s) allegedly meets each limitation of the asserted claims,
- (4) stating whether such alleged infringement is literal or under the doctrine of equivalents, including for any assertion under the doctrine of equivalents, the bases for such assertions;
- (5) stating whether such infringement is direct and/or contributory and/or active inducement of infringement, including a detailed explanation of the bases for such assertions, and
- (6) identifying all factual bases and evidentiary support that You intend to rely on in connection with Your assertions of infringement, all documents You contend support Your contentions, and the persons most knowledgeable about the information requested in this interrogatory.

ANSWER:

- (1) According to information and belief, the Nanobio Protect product infringes at least claims 1, 2, 6, and 7 of the '802 Patent by the commercial manufacture, use, offer for sale, sales, and/or importation of the product. According to information and belief, each of the BlueWillow vaccine products containing a nanoemulsion adjuvant infringes at least claims 1 and 2 of the '802 Patent by the commercial manufacture, use, offer for sale, sales, and/or importation of that product. According to information and belief, the BlueWillow vaccines

that are intended to produce an immune response in subjects to harmful diseases and conditions, and which read on at least claims 1 and 2 of the '802 Patent include but are not limited to:

- (a) anthrax,
 - (b) influenza,
 - (c) COVID-19 and its variants,
 - (d) RSV (Respiratory Syneytial Virus),
 - (e) SARS,
 - (f) sexually transmitted diseases,
 - (g) environmental allergies,
 - (h) food allergies,
 - (i) peanut allergies, and
 - (j) certain forms of cancer.
- (2) According to information and belief, the Nanobio Protect product infringes at least claims 1, 2, 6, and 7 of the '802 Patent. According to information and belief, each of the BlueWillow vaccine products containing a nanoemulsion adjuvant indicated *supra* infringes at least claims 1 and 2 of the '802 Patent.
- (3) According to information and belief, the Nanobio Protect product infringes claim 1 because:
- (a) the product is a formulation that is applied to the skin or tissue of the nasal passages of the user in a thin film;
 - (b) the product electrostatically attracts harmful particulate matter to the thin film;
 - (c) the product holds the harmful particulate matter to the thin film, which sticks to the skin or tissue of the nasal passages; and
 - (d) the product inactivates the harmful particulate matter by adding benzalkonium chloride ("BZK"), which renders the particulate matter harmless.

According to information and belief, the Nanobio Protect product infringes claim 2 because:

- (a) the product is a formulation that is applied to the skin or tissue of the nasal passages of the user in a thin film;
- (b) the product is a formulation that contains a cationic agent.
- (c) the product is a formulation that contains a biocidal agent.
- (d) the product electrostatically attracts harmful particulate matter to the thin film;

- (e) the product holds the harmful particulate matter to the thin film, which sticks to the skin or tissue of the nasal passages; and
- (f) the product inactivates the harmful particulate matter by adding benzalkonium chloride ("BZK"), which renders the particulate matter harmless.

According to information and belief, the Nanobio Protect product infringes claim 6 because its formulation contains BZK, which is a known cationic agent.

According to information and belief, the Nanobio Protect product infringes claim 7 because its formulation contains BZK, which is a known biocidal agent.

According to information and belief, all of the BlueWillow vaccines *supra* all infringe claim 1 because:

- (a) their formulations each contain a nanoemulsion, which by nature comprises electrostatically charged sub-micron sized droplets;
- (b) their formulations comprising the sub-micron sized droplets are applied to the skin or tissue of the nasal passages in a thin film;
- (c) because of the electrostatic charges of the sub-micron sized droplets, the droplets attract harmful particulate matter to the thin film which sticks to the skin or tissue of the nasal passages;
- (d) because of the electrostatic charges of the sub-micron sized droplets, the droplets hold the harmful particulate matter to the thin film, which sticks to the skin or tissue of the nasal passages; and
- (e) the product inactivates the harmful particulate matter by adding at least one ingredient, which renders the particulate matter harmless.

According to information and belief, the BlueWillow vaccines *supra* all infringe claim 2 because:

- (a) their formulations contain a cationic agent.
- (b) their formulations contain a biocidal agent.
- (c) their formulations each contain a nanoemulsion, which by nature comprises electrostatically charged sub-micron sized droplets;
- (d) their formulations comprising the sub-micron sized droplets are applied to the skin or tissue of the nasal passages in a thin film;
- (e) because of the electrostatic charges of the sub-micron sized droplets, the droplets attract harmful particulate matter to the thin film which sticks to the skin or tissue of the nasal passages;

- (f) because of the electrostatic charges of the sub-micron sized droplets, the droplets hold the harmful particulate matter to the thin film, which sticks to the skin or tissue of the nasal passages; and
 - (g) the product inactivates the harmful particulate matter by adding at least one ingredient, which renders the particulate matter harmless.
- (4) According to information and belief, infringement by the Nanobio Protect product and by the BlueWillow vaccines *supra* is literal. At this time, Plaintiff is unaware whether there is contributory and/or active inducement of infringement or whether these products infringe according to the Doctrine of Equivalents.
- (5) According to information and belief the detailed basis for asserting direct infringement by the Nanobio Protect product and by the BlueWillow vaccines *supra* is contained in sub-paragraphs (1) through (3) *supra*.
- (6) The bases are both experimental and theoretical and has been already presented or will be presented in evidence as past and present versions of Defendant's website (www.bluewillow.com), report of Dr. Alexei Ermakov, the report of Electro-Tech Systems, Inc. (by Shane Burns and Troy Anthony), and information presented to Plaintiff by Ashok Wahi and Dr. Edward A. Lemmo. Evidentiary testimony from additional experts will be presented in the future.

INTERROGATORY No. 3

To the extent You dispute any of BlueWillow's contentions of invalidity, describe in detail what is disputed and why, and identify all documents, things, and witnesses that You rely on as the basis for such dispute.

ANSWER:

The Defendant has the burden of proof of invalidity of the '802 patent according to a clear and convincing evidentiary standard. The Defendant has thus far presented no rationale for invalidity of the '802 Patent or any evidence thereto. In the Third Affirmative Defense pled in Defendant's Answer of May 19, 2021 to the Complaint, Defendant stated that, "[t]he claims of the '802 patent are invalid, including for, among other reasons, failure to meet one or more of the requisite requirements and/or conditions for patentability in 35 U.S.C. §§ 101, 102, 103 and 112." The Defendant failed to state how or why the claims of the '802 Patent are invalid under each of these four statutes. Further, the Defendant stated that, "at least the following prior art references render each claim of the '802 Patent invalid under 35 U.S.C. § 102 and/or § 103: U.S. Patent No. 6,559,189; U.S. Patent No. 6,506,803; U.S. Patent No. 10,138,279; U.S. Published Application No. 2006/0163149; U.S. Published Application No. 2004/0071757; and U.S. Patent No. 5,468,488." The Defendant failed to state (1) which claims of the '802 Patent are invalid based upon the aforementioned prior art references; (2) under which statute (§102 or §103) any claims of the '802 Patent are invalid; or (3) how and why these prior art references render any claims of the '802 Patent invalid. According to the law, the '802 Patent is presumed valid. Defendant has presented merely a scant allegation of invalidity. Until Defendant provides specific evidence of invalidity, Plaintiff is under no obligation to prove validity of the '802 Patent.

INTERROGATORY No. 4

If any person has ever contended that any claim of the asserted patent or related patents is invalid or unenforceable, including during the course of license or settlement negotiations with any person(s), identify the communication where such contention was made, including by identifying:

- (1) the person so contending;
- (2) each communication wherein such claim was alleged to be invalid or unenforceable;

- (3) the specific bases on which such claim was alleged to be invalid in the communication (e.g., 35 U.S.C. §§ 101, 102, 103, or 112) or the specific grounds of unenforceability;
- (4) any prior art mentioned or referenced in the communication, each limitation of each claim of the asserted patent or related patent alleged to have been found in the prior art, any specific combination or combinations of prior art that the person contended would have rendered the claim obvious to one of ordinary skill, what that person so contending alleged suggested such combination, combinations and/or motivation to deviate from or combine the art; and
- (5) any documents, by bates number, relating or referring to the communication.

ANSWER:

- (1) Matrixx Initiatives, Inc. of Bridgewater, New Jersey ("Matrixx") and Monsoor M. Amiji, Ph.D., R.Ph.
- (2) An *inter partes* review ("IPR") filed against the '802 Patent by Matrixx with the Patent Trial and Appeals Board (PTAB) of the United States Patent and Trademark Office (USPTO) - IPR2020-01592 filed on September 18, 2020.
- (3) All claims were alleged by Matrixx to be invalid under 35 U.S.C. § 103.
- (4) United States Patent Application Publication No. 2006/0163149 A1
United States Patent Application Publication No. 2004/0071757 A1
United States Patent No. 5,468,488
United States Patent No. 5,674,481
- (5) The petition for IPR2020-01592 was not generated by Plaintiff, Trutek Corp. However, it is available to the public on the USPTO PTAB website.

INTERROGATORY No. 5

To the extent You contend that any secondary considerations or objective indicia probative of non-obviousness of any asserted claim exists, describe in detail all facts and circumstances and identify all documents, witnesses, and things relating to such contention, including without limitation all facts and evidence on which You intend to rely to allege a nexus between such secondary considerations or objective indicia and the alleged invention covered by any asserted claim.

ANSWER:

Plaintiff objects to this interrogatory because it is unclear what is meant "secondary considerations or objective indicia probative of non-obviousness." Plaintiff is unable to answer this interrogatory because of the lack of clarity as to what the interrogatory requires.

INTERROGATORY No. 6

For each asserted claim, identify each claim term that You contend requires construction by the Court, and set forth in a chart Your proposed construction of each such claim term and identify all intrinsic and extrinsic evidence that You contend supports Your construction of each such claim term, including, without limitation, all citations to the claim language, any plain or ordinary meaning of words and phrases, any special or uncommon meanings of words or phrases, written description, prosecution history,

dictionaries, citations to learned treatises, and anticipated expert testimony, that supports Your construction.

ANSWER:

To the extent that there is disagreement between the parties regarding the meaning of the terms:

- (a) electrostatically inhibiting,
- (b) electrostatically attracts,
- (c) harmful particulate matter,
- (d) infecting an individual,
- (e) skin or tissue of nasal passages,
- (f) thin film,
- (g) cohesion,
- (h) adhesion,
- (i) holds,
- (j) adequate impermeability,
- (k) cationic agent,
- (l) biocidal agent, and/or
- (m) inactivates or inactivating,

Plaintiff with generate a Markman brief to be presented to the Court and will participate in a Markman hearing should the Court so decide.

INTERROGATORY No. 7

For each asserted claim of the asserted patent, describe in as much detail and specificity as known to You about the conception, reduction to practice (actual or constructive), and all activities constituting diligence from conception to reduction to practice of the purported invention of each claim of the asserted patent, including without limitation, including by identifying:

- (1) when, where, and by whom each claimed invention was conceived;

- (2) the specific contribution by each alleged inventor and any others working with such inventor;
- (3) the first written description of each claimed invention (including when and where it was made and by whom);
- (4) the earliest priority date of each claimed invention and all bases for such priority;
- (5) when, where, by whom, and under what circumstances each claimed invention was first reduced to practice; and
- (6) the first public disclosure, use, sale or offer for sale, of each claimed invention, including when, where, by whom, and to whom; and
- (7) all evidence and witnesses corroborating the above.

ANSWER:

- (1) Conception took place on or about early 2007 by Ashok Wahi in Somerville, New Jersey.
- (2) Ashok Wahi is the sole inventor of all claims of the '802 Patent.
- (3) The first written description of the invention and claims were generated by Stanley H. Kremen on July 6, 2008.
- (4) The earliest priority date of the claims of the '802 Patent is July 7, 2008 based on the filing of U.S. Provisional Application No. 61/078,478 at the USPTO.
- (5) Constructive reduction to practice took place on July 6, 2008, and actual reduction to practice took place sometime during May 2008 by Ashok Wahi at Trutek's laboratory in Somerville, New Jersey.
- (6) The first public disclosure took place on July 7, 2008 with the filing of Provisional Application No. 61/078,478 at the USPTO. The first offer for sale, took place sometime on or about April 12, 2013.
- (7) Person corroborating the above information is Shaheda Ashtekar, who was the office manager of Trutek at the time..

INTERROGATORY No. 8

Describe in detail each and every instance in which You licensed, attempted to license, offered to license, suggested a license under, discussed a license under, entered a covenant not to sue, entered a technology transfer agreement, or settled a lawsuit that relates to the subject matter of the asserted patent or related patents, including by identifying the persons, places, dates, and material terms associated with each instance.

ANSWER:

The answer to this interrogatory involves revelation of trade secrets by Plaintiff and revelation of confidences between Plaintiff and third parties. This information cannot be revealed absent a mutually agreed upon protective order by the Court. Further, the lawsuit between Trutek and Matrixx settled in December 2020. The terms of the settlement were filed with the Court under seal, and Plaintiff is prohibited from revealing the terms of settlement and/or the settlement agreement.

INTERROGATORY No. 9

Identify each person you anticipate will testify in this Action, including by providing such person's name, employer, title, and a detailed explanation of and summary of the person's anticipated testimony.

ANSWER:

- Ashok Wahi - Trutek Corp. - evidence regarding the '802 Patent and testing of Nanobio Protect product.
- Alexei Ermakov, Ph.D. - evidence regarding testing of BlueWillow products.
- Shane Burns or Troy Anthony - Electro-Tech Systems, Inc. - evidence regarding testing of BlueWillow products.
- Edward A. Lemmo, Ph.D. - expert testimony regarding BlueWillow products.
- Dennis M. O'Donnell, R.Ph. - Primus Advisors LLC - expert testimony regarding BlueWillow products.
- At least one additional expert to testify regarding damages.
- At least one additional expert to testify regarding patent validity.

INTERROGATORY No. 10

Identify and describe in detail all damages that you seek to recover in this Action, including an accounting of the specific categories of damages claimed (e.g., lost profits, reasonable royalty, or any other category you claim to have suffered as a result of any conduct by BlueWillow), the amount for each category and how it was calculated, the legal and factual bases supporting your claim for damages, all documents and evidence upon which you rely for your calculations, and the persons most knowledgeable about the information requested in this interrogatory.

ANSWER:

The NanoBio Protect product is no longer being sold. BlueWillow took the product off the market sometime in mid-2021. However, the start date and end date of this product's sales is unknown. Because this product infringes upon the '802 Patent, every sale of this product made by BlueWillow should have accrued to Trutek. Therefore, Plaintiff seeks the

profit from every sale. The method of calculation of lost profits will be presented by an expert yet to be engaged.

According to information and belief, the BlueWillow vaccines are not yet commercialized. It is therefore not feasible to compute past, present, or future damages. Instead, Plaintiff seeks injunctive relief that would allow it to protect its patent rights.

INTERROGATORY No. 11

To the extent You claim entitlement to damages on a theory of lost profits, identify each and every instance in which You contend You lost a sale as a result of the alleged infringement of a claim of the asserted patent by BlueWillow or any other person or entity, including by identifying:

- (1) the entity to whom You contend it lost a sale as a result of the alleged infringement;
- (2) the customer or potential customer to whom the sale was made;
- (3) the date or approximate date of the same;
- (4) the product offered or proposed to the customer;
- (5) the person(s) at the customer most knowledgeable about the proposed transaction;
- (6) the person(s) most knowledgeable about the proposed transaction; and
- (7) the persons most knowledgeable about the information requested in this interrogatory and all documents related thereto.

ANSWER:

At present, Plaintiff has received no detailed discovery from Defendant regarding sales of its products. Therefore, Plaintiff objects to this interrogatory. It is unable to answer it at this time.

INTERROGATORY No. 12

Identify and describe any product or process made or used by anyone other than BlueWillow, including any product or process made or used by You or a third party, which You contend is covered by any of the claims of the asserted patent, including by identifying:

- (1) any code name, prototype name, model name, model number, and any other identifying designation, and time period sold;
- (2) whether any such products or processes have been marketed, advertised, or marked as being covered by the asserted patent (for each such product or process state which claim covers it);
- (3) for each such product or process identify the date of its first sale, offer for sale and/or public use in the United States and the persons most knowledgeable regarding the first offer for sale and public use; and
- (4) for each such product or process identify the persons most knowledgeable about the information requested in this interrogatory and all documents related thereto.

ANSWER:

- (1) The answer to this interrogatory involves revelation of trade secrets by Plaintiff and/or revelation of confidences between Plaintiff and third parties. This information cannot be revealed absent a mutually agreed upon protective order by the Court.
- (2) The answer to this interrogatory involves revelation of trade secrets by Plaintiff and/or revelation of confidences between Plaintiff and third parties. This information cannot be revealed absent a mutually agreed upon protective order by the Court.
- (3) The answer to this interrogatory involves revelation of trade secrets by Plaintiff and/or revelation of confidences between Plaintiff and third parties. This information cannot be revealed absent a mutually agreed upon protective order by the Court.

- (4) Ashok Wahi is the person most knowledgeable regarding sub-paragraphs (1) through (3), *supra*.

INTERROGATORY No. 13

For each product or process responsive to Interrogatory No. 12, provide a detailed explanation of how the product or process was marked pursuant to 35 U.S.C. § 287(a), including by providing:

- (1) a description of all time periods it was marked with the patent number of the asserted patent;
- (2) a description of all time periods it was made, used, sold or offered for sale in, or imported into, the United States;
- (3) a description, in an element-by-element chart, of how each asserted claim of the asserted patent reads on the product or process; and
- (4) an identification of all documents describing or supporting any of the information requested by this Interrogatory and the persons most knowledgeable regarding such information.

ANSWER:

- (1) Because the answer to this interrogatory depends from Interrogatory No. 12, it involves revelation of trade secrets by Plaintiff and/or revelation of confidences between Plaintiff and third parties. This information cannot be revealed absent a mutually agreed upon protective order by the Court.
- (2) Because the answer to this interrogatory depends from Interrogatory No. 12, it involves revelation of trade secrets by Plaintiff and/or revelation of confidences between Plaintiff and third parties. This information cannot be revealed absent a mutually agreed upon protective order by the Court.
- (3) Because the answer to this interrogatory depends from Interrogatory No. 12, it involves revelation of trade secrets by Plaintiff and/or revelation

of confidences between Plaintiff and third parties. This information cannot be revealed absent a mutually agreed upon protective order by the Court.

- (4) Because the answer to this interrogatory depends from Interrogatory No. 12, it involves revelation of trade secrets by Plaintiff and/or revelation of confidences between Plaintiff and third parties. This information cannot be revealed absent a mutually agreed upon protective order by the Court.

Dated May 11, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on May 11, 2022, I served the foregoing Plaintiff's Answers to Interrogatories upon all parties via email.

A handwritten signature in black ink, appearing to read 'Keith Altman', is written over a horizontal line.

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